



Patent  
Customer No. 22428  
Atty. Dkt. No. 67242/107

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Fumihiko WATANABE et al.

Title: SULFONATED AMINO ACID DERIVATIVES AND  
METALLOPROTEINASE INHIBITORS CONTAINING  
THE SAME

Appl. No.: 09/120,383

Filing Date: 07/22/1998

Examiner: Samuel Barts

Art Unit: 1621

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.97(b)**

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants brings to the Examiner's attention the documents listed on the attached PTO/SB/08. This Information Disclosure Statement is being filed with an RCE.

Copies of the listed documents are attached. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

Documents A1- A4 on the attached PTO/SB/08 were cited during the prosecution of the corresponding European application. A copy of the European Search Report is attached. Applicants note that Document A4 was previously submitted with an Information Disclosure Statement filed in the present application on September 7, 2000. However, since the reference has not yet been acknowledged by the Examiner, Document A4 is being re-submitted with the present Information Disclosure Statement. All other documents cited in

the European Search Report have been submitted in a previously filed Information Disclosure Statements and acknowledged by the Examiner. Therefore, these documents are not being submitted with the present Information Disclosure Statement.

Additionally, the documents that are identified by a number preceded by "B" (e.g., B1, B2, etc.) were served but never filed during the interference.

This submission does not represent that a search has been made or that no better art exists. The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 2/5/4

FOLEY & LARDNER  
Customer Number: 22428  
Telephone: (202) 672-5569  
Facsimile: (202) 672-5399

By Stephen B. Maebius (45,943)  
For SEAN A. PASSINO  
Stephen B. Maebius  
Attorney for Applicants  
Registration No. 35,264

Enclosure: European Search Report for EP 97 90 0747

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: February 5, 2004  
(use as many sheets as necessary)

Sheet 1 of 4

## Complete if Known

Application Number	09/120,383
Filing Date	07/22/1998
First Named Inventor	Fumihiko Watanabe
Group Art Unit	1621
Examiner Name	Samuel Barts

Attorney Docket Number 67242/107

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	B1	3,784,701		TOMCUFICIK ET AL	01-09-1974	
	B2	4,269,775		SZCZEPANSKI ET AL.	05-26-1981	
	B3	4,388,464		KRISTINSSON ET AL.	06-14-1983	
	B4	4,599,361		DICKENS ET AL.	07-08-1986	
	B5	4,632,931		NAKANE	12-30-1986	
	B6	4,715,883		LUKASZCZYK ET AL.	12-29-1987	
	B7	5,270,326		GALARDY ET AL.	12-14-1993	
	B8	6,294,674		PICARD	09-25-2001	
	B9	6,117,869		PICARD	09-12-2000	
	B10	6,150,394		WATANABE ET AL.	11-21-2000	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
✓	A1	WO	95/13064		A1 BRITISH BIOTECH PHARMACEUTICALS LIMITED	05-18-1995		
✓	B11	EP	305 947		MOCHIDA ET AL.	03-08-1989		
✓	B12	EP	548 798		KURONO ET AL.	06-30-1993		
✓	B13	EP	606 046		MACPHERSON ET AL.	07-13-1994		
✓	B14	WO	94/12181		EBERTSON ET AL.	06-09-1994		
✓	B15	WO	95/13289		MONTANA ET AL.	05-18-1995		
✓	B16	WO	95/35275		MILLER ET AL.	12-28-1995		
✓	B17	WO	95/35276		MILLER ET AL.	12-28-1995		
✓	B18	WO	96/00214		MACPHERSON ET AL.	01-04-1996		
✓	B19	WO	96/11209		MONTANA ET AL.	04-18-1996		
✓	B20	WO	96/15096		KLUENDER ET AL.	05-23-1996		
✓	B21	WO	93/14069		BOWLES ET AL.	07-22-1993		
✓	B22	WO	97/45402		TAKAHASHI ET AL.	12-04-1997		
✓	B23	EP	757 037		SAKAKI ET AL.	02-05-1997		
✓	B24	EP	757 984		SAKAKI ET AL.	02-12-1997		
✓	B25	EP	468 231		ACKERMANN ET AL.	01-29-1992		
✓	B26	JP	57-59969			04-10-1982		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
--------------------	-----------------------	--	----------------

#1146083

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> FEB. 05 2004 Date Submitted: February 5, 2004 Use as many sheets as necessary)				<b>Complete if Known</b>	
Sheet	2	of	4	Application Number	09/120,383
				Filing Date	07/22/1998
				First Named Inventor	Fumihiko Watanabe
				Group Art Unit	1621
				Examiner Name	Samuel Barts
				Attorney Docket Number	67242/107

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sub>6</sub>
✓	A2	DATABASE CAPLUS 'OnLine', CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; retrieved from STN, Database accession no. 1993:626388, XP002230555, *abstract; RN 150782-45-9, 150782-77-7, 150782-48-2, 150782-51-7, 150782-72-2, 150782-47-1, 150782-49-3, 150782-50-6, 150782-73-3, 150782-70-0 * & M.H. EL-HAKIM: AL-AZHAR BULL. SCI., vol. 3, no. 1, 1992, pp. 9-17.			
✓	A3	EL-SAYED, R.A., "Some novel sulfamyl amino acid derivatives," J. SERB. CHEM. SOC., vol. 56, no. 6, 1991, pp. 311-318, XP000882133.			
✓	A4	ROEMMLE ET AL., "Removal of N-Arylsulfonyl Groups from Hydroxy $\alpha$ -Amino Acids," J. ORG. CHEM., vol. 53, no. 10, 1988, pp. 2367-2371, XP002230552.			
✓	B27	BEILSTEIN reference 5115437			
✓	B28	YE, ET AL., "Purification and Characterization of the Human Stromelysin Catalytic Domain Expressed in <i>Escherichia coli</i> ," BIOCHEMISTRY, vol. 31, No. 45, pp. 11231-11235, 1992.			
✓	B29	CHAPMAN ET AL., "Inhibition of Matrix Metalloproteinases by N-Carboxyalkyl Peptides," J. MED. CHEM., vol. 36, No. 26, pp. 4293-4301, 1993.			
✓	B30	WILHELM ET AL., "SV40-transformed Human Lung Fibroblasts Secrete a 92-kDa Type IV Collagenase Which is Identical to That Secreted by Normal Human Macrophages," The JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 264, No. 29, pp. 17213-17221, 1989.			
✓	B31	OKADA ET AL., "Matrix Metalloproteinase 9 (92-kDa Gelatinase/Type IV Collagenase) from HT 1080 Human Fibrosarcoma Cells," JOURNAL OF BIOLOGICAL CHEMISTRY, vol. 267, No. 30, pp. 21712-21719, 1992.			
✓	B32	WARD ET AL., "The Purification of Tissue Inhibitor of Metalloproteinases-2 from its 72 kDa Progelatinase Complex," BIOCHEMICAL JOURNAL, vol. 278, pp. 179-187, 1991.			
✓	B33	DEBNATH ET AL., "4-(4'-Substituted benzoyl) aminobenzenesulphonyl-L(+)-glutamic acids and 5-N-substituted-2-[4'-(4"-substituted benzoyl)aminobenzenesulphonyl]-L-glutamines as potential antineoplastic agents: Synthesis, biological evaluation and quantitative structure-activity relational studies," INDIAN JOURNAL OF CHEMISTRY, vol. 28B, pp. 843-847, 1989.			
✓	B34	GALLI ET AL., "Table II Enantiomeric Resolution of Dbs-Amino Acids on (S)-PheA-CSP," J. CHROMATOGR. A 666, pp. 77-89, 1994.			
✓	B35	HANSEN ET AL., "Oxazoline Formation via a Palladium-catalyzed Cyclization: A Direct, Stereoselective Approach to cis-5-Amino-2-cyclopenten-1-ol Derivatives," TETRAHEDRON LETTERS, vol. 16, pp. 2913-2916, 1995.			

#1146083

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<p style="text-align: center;">Substitute for form 1449B/PTO</p> <p style="text-align: center;"><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p style="text-align: center;">FEB 05 2004</p> <p>Date Submitted: February 5, 2004</p> <p style="text-align: center;">(use as many sheets as necessary)</p> <p>Sheet 1 of 4</p>				<b>Complete if Known</b>	
				Application Number	09/120,383
				Filing Date	07/22/1998
				First Named Inventor	Fumihiko Watanabe
				Group Art Unit	1621
				Examiner Name	Samuel Barts
				Attorney Docket Number	67242/107

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sub>6</sub>
✓	B36	HALVACEK ET AL., "An Alternative Route to N <sup>α</sup> -Methylamino Acid Derivatives: Synthesis and Conformation of some N <sup>α</sup> -Acetyl-N <sup>α</sup> -Methylamino Acid Methylamides," COLLECTION CZECHOSLOVAK CHEM. COMMUN., vol. 53, pp. 2473-2494, 1988.	
✓	B37	KAISER ET AL., "2-Substituted Derivative of 3,4-Dihydroxyphenylalanine," vol. 79, pp. 4365-4379, 1957.	
✓	B38	LEE ET AL., "Systematic study on the resolution of derivatized amino acids enantiomers on different cyclodextrin-bonded stationary phases," J. OF CHROMATOGRAPHY, 603, pp. 83-93, 1992.	
✓	B39	LIN ET AL., "Debsyl Chloride: Its Synthesis, Characterization and Application in Amino Acid and Amine Microanalysis," JOURNAL OF THE CHINESE BIOCHEMICAL SOCIETY, vol. 14, No. 1, pp. 10-19, 1985.	
✓	B40	NATELSON ET AL., "Preparation of D-,DL-, and L-Homoserine Lactone from Methionine," MICROCHEMICAL JOURNAL 40, pp. 226-232, 1989.	
✓	B41	NICKEL ET AL., "Carboxylic acid analogues of suramin, potential filaricides," INDIAN JOURNAL OF CHEMISTRY, vol. 30B, pp. 182-187, 1991.	
✓	B42	STOCCHI ET AL., "Reversed-Phase High-Performance Liquid Chromatography Separation of Dimethylaminoazobenzene Sulfonyl-and Dimethylaminoazobenzene Thiohydantoin-Amino Acid Derivative for Amino Acid Analysis and Microsequencing Studies at the Picomole Level," BIOCHEMISTRY, 178, pp. 107-117, 1989.	
✓	B43	VERDERAME, "Sulfide Derivatives of Cysteine II," JOURNAL OF PHARMACEUTICAL SCIENCES, vol. 51, No. 6, pp. 576-579, 1962.	
✓	B44	YONEDA ET AL., "Reactions of L- $\alpha$ -Tosylamido- $\beta$ -propiolactone: Synthesis, Reactions with Amines and Derivation to L-Seriene," UDC, vol. 89, pp. 98-103, 1969.	

#1146083

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Date Submitted: February 5, 2004

(Use as many sheets as necessary)

Sheet

4

of

4

## Complete if Known

Application Number	09/120,383
Filing Date	07/22/1998
First Named Inventor	Fumihiko Watanabe
Group Art Unit	1621
Examiner Name	Samuel Barts
Attorney Docket Number	67242/107

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sub>6</sub>
✓	B45	KSANDER ET AL., "Dicarboxylic Acid Dipeptide Neutral Endopeptidase Inhibitors," J. MED. CHEM., 38, pp. 1689-1700, 1995.	
✓	B46	SHIN-ZIKKENKAGAKUKOZA, vol. 14, 1787, 1978.	
✓	B47	HAMADA ET AL., "An Improved Synthesis of Arylsulfonyl Chlorides from Aryl Halides," COMMUNICATIONS, pp. 852 – 854, 1986.	
✓	B48	SONOGASHIRA ET AL., "A Convenient Synthesis of Acetylenes: Catalytic Substitutions of Acetylenic Hydrogen with Bromoalkenes, Iodoarenes, and Bromopyridines," TETRAHEDRON LETTERS, No. 50, pp. 4467-4470, 1975.	
✓	B49	SHARP ET AL., "Synthetic Connections to the Aromatic Directed Metalation Reaction. Unsymmetrical Biaryls by Palladium-Catalyzed Cross Coupling of Directed Metalation-Derived Arylboronic Acids with Aryl Halides," TETRAHEDRON LETTERS, vol. 26, No. 49, pp. 5997-6000, 1985.	
✓	B50	WITTIG ET AL., "Über Triphenyl-phosphin-methylene als olefinbildende Reagenzien (I. Mitteil.)," ALS OLEFINBILDENDE REAGENZIEN, No. 9, pp. 1318-1330, 1954.	
✓	B51	MORPHY, ET AL., "Matrix Metalloproteinase Inhibitors: Current Status," CURRENT MED. CHEM. 1995, vol. 2, pp. 743-762, 1995.	
✓	B52	JG TOPLISS ET AL., Drug Design, (1975) Vol. 5, pp. 1-21 (Academic Press, London).	
✓	B53	OECD Guideline for the Testing of Chemicals.	

#1146083

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.